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K004006 1/2

Attachment 13
510(k) Summary
Coherent Selecta 7000

I. General Information

Applicant:	Coherent Medical Group 2400 Condensa Street Santa Clara, California 95051-0901
Contact Person:	Karen L. Baker
Summary Preparation Date:	December 22, 2000

II. Names

Device Name:	Coherent Selecta 7000 Frequency Doubled Q-Switched Nd:YAG Ophthalmic Laser
Primary Classification Name:	Laser, Ophthalmic; Laser, Powered Surgical Instrument

III. Predicate Devices

The Coherent Selecta 7000 is substantially equivalent to the currently marketed Coherent Ultima 2000 Argon Ophthalmic Laser, Laserex LP1532 Nd:YAG Photocoagulator, the Alcon Ophthalas 532 Solid State Photocoagulator, and the Lasag Microruptor 2 Nd:YAG Ophthalmic Laser.

IV. Product Description

The Coherent Selecta 7000 is a frequency doubled, Q-switched Nd:YAG laser which delivers single laser pulses of 0.1 to 2.0 millijoules per pulse with a pulse duration of approximately 3 nanoseconds. This low energy, short pulsed laser treatment confines thermal damage to trabecular meshwork cells containing the target pigment or chromophore. The following functional components comprise the Coherent Selecta 7000:

- Electronics Module
- Laser Optical Head
- Control Panel
- Slit Lamp/Slit Lamp Table
- Covered Footswitch

K004006 2/2

V. Indication for Use

The Coherent Selecta 7000 is indicated for use in laser trabeculoplasty in patients with open angle glaucoma.

VI. Rationale for Substantial Equivalence

The Coherent Selecta 7000 shares the same indication for use and similar design features (including laser media, treatment wavelength, mode of operation, treatment area, aiming beam, delivery system, cooling system, and control system) as the predicate devices. The Coherent Selecta 7000 has different functional features from the predicate devices, including energy delivered and spot size. The effects of the new functional features in performing trabeculoplasty have been assessed through that the Coherent Selecta 7000 is substantially equivalent to the predicate laser systems.

VII. Performance Data

In vitro, *ex vivo*, and *in vivo* testing was conducted to demonstrate that the Coherent Selecta 7000 is substantially equivalent to predicate lasers used for laser trabeculoplasty.

In addition, system and software hazard analysis information and software verification and validation information were provided in this Premarket Notification submission.

VIII. Conclusion

The Coherent Selecta 7000 is substantially equivalent to currently marketed predicate laser devices. The Coherent Selecta 7000 shares the same intended use and indication for use and other basic system characteristics as the predicate laser systems. Preclinical testing demonstrates the substantial equivalence of the Coherent Selecta 7000 for use in trabeculoplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

Ms. Karen L. Baker
Manager, Regulatory Affairs
Coherent Medical Group
2400 Condensa Street
Santa Clara, California 95051-0901

Re: K004006
Trade Name: Coherent Selecta 7000 Frequency Doubled Q-Switched Nd:YAG Ophthalmic Laser
Regulatory Class: II
Product Code: GEX, HQF
Dated: December 22, 2000
Received: December 26, 2000

Dear Ms. Baker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested by FDA

510(k) Number (if known): K004006

Device Name: **Coherent Selecta 7000 Frequency Doubled, Q-Switched Nd:YAG Ophthalmic Laser**

Indications for use:

The Coherent Selecta 7000 is intended for use in ophthalmic applications using laser energy emitted by a frequency doubled, Q-switched Nd:YAG laser.

- The Coherent Selecta 7000 is indicated for use in laser trabeculoplasty

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K004006

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Optional Format 1-2-96